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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,804	07/28/2003	Arlene R. Howe	38-21(15060)C	4557

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,804	HOWE ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4-6, 8-10, 13-18, 21-23, 25-27, 30-33 and 38-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,8-10,13-18,21-23,25-27,30-33,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4-6, 8-10, 13-18, 21-23, 25-27, 30-33 and 38-39 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 3 and 20 under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 13 of prior U.S. Patent No. 6,600,088 is withdrawn in light of their cancellation.

4. The rejection of claims 11-15 and 28-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

Claim Objections

5. Claim 1 is objected to because --geneticin-- is misspelled as "genenticin"

Claim Rejections - 35 USC § 112

6. Claims 1, 4-6, 8-10, 13-18, 21-23, 35-27, 30-33 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of an NPTII selectable marker gene in a plant using kanamycin and paromomycin and certain organosilicone concentrations, does not reasonably provide enablement for a method of detecting the presence of any selectable marker gene in a plant using all the listed selective agents and organosilicone concentrations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2005, as applied to claims 1-2, 4-19, 21-33 and 38-39. Applicant's arguments filed 7 April 2005 have been fully considered but they are not persuasive.

The claims are drawn very broadly to a method of detecting the presence of any selectable marker gene product in any plant by applying or contacting a plant of any species and of any age with any amount of any selective agent and any organosilicone surfactant and assessing the resulting appearance of the plant. Some of the claims specify a particular surfactant, surfactant concentration, selective agent, selectable marker gene, or plant type or species, but no claims are limited to all these features, so that, for example, the claims that specify a particular surfactant at a particular concentration, call for the use of the method in any plant with any selectable marker gene/selectable agent combination. The specification lacks guidance for carrying out the method of detecting a selectable marker gene, particularly one other than the NPTII gene.

The direct application of a selectable marker and a surfactant to plants is unpredictable. The instant specification indicates that use of the organosilicone SILWET L-77 at concentrations above 0.1% resulted in obvious yellowing of the leaves of nontransgenic corn seedlings of an unspecified age (page 13, lines 5-6). All the further examples use SILWET L-77 concentrations in the range of 0.01%-0.06%, so the effect of the yellowing caused by the higher SILWET L-77 concentrations on the ability to score treated plants for necrosis and/or bleaching caused by the presence of a selective agent was not determined. Severe yellowing would likely interfere with

the ability to score the plants, and the specification gives no guidance on how to score treated plants when high SILWET L-77 concentrations are used.

The behavior of different organosilicone surfactants is unpredictable. The bulk of the examples are done using a single organosilicone surfactant, SILWET L-77, but example 9 (pg 18-19 of the specification) shows the results when kanamycin/paromomycin mixture was applied to nontransformed corn seedlings using different SILWET surfactants. In the tests with one of the surfactants, SILWET L-7002, one plant out of six tested showed no visible bleaching. This suggests that not all organosilicone surfactants would behave as SILWET L77 does, and that false positives would be seen when some organosilicone surfactants are used.

These claims encompass all or many herbicide and antibiotic selectable agents and corresponding resistance genes. However, not all antibiotics to which even a single resistance gene confers resistance would respond in the same manner. The instant specification indicates that while the NPTII gene product confers resistance to a number of antibiotics including genenticin and kanamycin, genenticin did not give a clearly defined bleaching and/or necrosis response on nontransgenic corn seedlings, while kanamycin, at least at some concentrations, did (pg 13 of the specification, example 2). Additionally, paromomycin, when used with SILWET L-77 as the only antibiotic on nontransformed corn plants produced a number of plants with no symptoms, *i.e.*, it generated false positives (table on pg 16 of the specification). If three antibiotics that correspond to a single resistance gene behave unpredictably, it is reasonable to expect that antibiotics or herbicides that correspond to other resistance genes would also behave in an unpredictable manner, and that guidance for their use would be required.

The amount of antibiotic and organosilicone needed as a function of the age of the plants is unpredictable. Example 4 of the specification (pg 15) indicates that corn seedlings of different ages needed very different amounts of antibiotic to produce visible necrosis or bleaching. For 1-week-old corn seedlings, 0.01 mg of antibiotic produced "very dramatic bleaching and necrosis' (lines 11-12), while for corn seedlings two weeks older, 2 to 2.5 times that amount of antibiotic produced only "some bleaching and necrosis" on the leaves (lines 18-20). Plants, corn or otherwise, older than that were not tested, and as the amount of bleaching and necrosis decreased with age of the plant, even when increased amounts of antibiotic were used, guidance would be needed for the application of the method to corn plants older than 3 weeks, soybeans other than 17 days old, and to other plants of any age.

Some markers that work in selection of transformed dicots do not work in selection of monocots. Dekeyser et al (1989, Plant Physiol. 90:217-223) teach that selection of untransformed rice calli by certain selective agents, including kanamycin, is very concentration dependent (pg 221-222, including figure 6). Hauptmann et al (1988, Plant Physiol. 86:602-606) teach that selection of NPTII transformants of *Lolium multiflorum* only works with G418 (geneticin) (pg 602, 1st full paragraph), which as discussed above, did not work in this assay, and that the Pennisetum spp. tested had high natural resistance to kanamycin (pg 603, right column). Zhou et al (1995, Plant Cell Rep. 15: 159-163) summarize some of the problems with the use of various selective agents in the transformation of monocots, and state that "few selectable markers are currently available for genetic transformation of monocot species" (paragraph spanning the columns on pg 159). Thus, guidance is required for the use of this method for the detection of any selectable marker gene product in any plant.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate this method for detecting the presence of any selectable marker gene product in any plant. There is no claim enabled for all the features noted above.

Applicant urges that one of skill in the art is readily familiar with selection agents that can be substituted for kanamycin and paromomycin, and no undue experimentation would be required to use them (response pg 6).

This is not found persuasive. The specification teaches that genenticin did not give a clearly defined bleaching and/or necrosis response on nontransgenic corn seedlings (pg 13 of the specification, example 2). Additionally, paromomycin, when used with SILWET L-77 as the only antibiotic on nontransformed corn plants generated false positives (table on pg 16 of the specification).

Applicant urges that concentrations of surfactant can readily determined, and the Applicant guides the artisan to some preferred ranges; other ranges can be tested without undue experimentation (response pg 6).

This is not found persuasive. The instant specification indicates that use of the organosilicone SILWET L-77 at concentrations above 0.1% resulted in obvious yellowing of the leaves of nontransgenic corn seedlings of an unspecified age (page 13, lines 5-6). This teaches against the use of concentrations above that, as claimed in claim 13. Severe yellowing would likely interfere with the ability to score the plants, and the specification gives no guidance on how to score treated plants when high SILWET L-77 concentrations are used.

Double Patenting

7. Claims 1, 4-6, 8-10, 13-18, 21-23, 35-27, 30-33 and 38-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-12 and 14-27 of U.S. Patent No. 6,600,088. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2005, as applied to claims 1-2, 4-19, 21-33 and 38-39. Applicant's arguments filed 7 April 2005 have been fully considered but they are not persuasive.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The method of detecting the presence of the selectable marker gene product NPTII protein, as claimed in the issued patent, is a species of the genus of methods of detecting the presence of the selectable marker gene product as claimed in the issued patent.

Applicant urges that a terminal disclaimed will be filed upon indication that the claims are otherwise allowable (response pg 6).

This is acknowledged.

Conclusion

8. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
June 14, 2006